



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,141	06/16/2005	Simon Murray Cooper	PG5049USw	2235
23347	7590	01/22/2010		
GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B482 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398			EXAMINER MCKANE, ELIZABETH L	
			ART UNIT 1797	PAPER NUMBER
			NOTIFICATION DATE 01/22/2010	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USCIPRTP@GSK.COM  
LAURA.M.MCCULLEN@GSK.COM  
JULIE.D.MCFALLS@GSK.COM

<b>Office Action Summary</b>	<b>Application No.</b> 10/539,141	<b>Applicant(s)</b> COOPER ET AL.	
	<b>Examiner</b> ELIZABETH L. MCKANE	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 11, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Subramaniam et al. (US 6,113,795).

Subramaniam et al. teaches a semi-continuous method for producing a particulate pharmaceutical product. The method of Subramaniam et al. includes providing a non-supercritical liquid solution having a pharmaceutical product dissolved therein which is fed into a particle formation vessel **32** by pump **18**. A supercritical fluid antisolvent **23,21** is provided by pump **20,22** into the particle formation vessel. See Figure 1. The non-supercritical liquid and the supercritical antisolvent are combined at a pressure above the supercritical point of the supercritical fluid, causing precipitation of the pharmaceutical product. See col.6, lines 1-14. The particulate pharmaceutical product is subsequently isolated from the combined fluids. See col.6, lines 15-31. The step of isolating the pharmaceutical product occurs when the pressure is dropped, converting the CO<sub>2</sub> from a supercritical to a non-supercritical fluid. Thus, the pharmaceutical product is suspended in a non-supercritical fluid. See specifically, col.7, lines 35-37. Subramaniam et al. further discloses that the process can be alternatively a continuous process. See col.7, lines 40-42.

### ***Response to Arguments***

3. Applicant's arguments filed 13 October 2009 have been fully considered but they are not persuasive.

4. Applicant argues on page 4 of the Response that Subramaniam et al. fails to isolate particulate in a non-supercritical fluid because the feed output **64** contains only CO<sub>2</sub> and drug particles. However, Subramaniam et al. also teaches that the reduction of pressure permits separation of the particles from the supercritical CO<sub>2</sub>. It is this same reduction of pressure that will cause the CO<sub>2</sub> to be non-supercritical. At this point, the CO<sub>2</sub> becomes a non-supercritical fluid, as required by the claims.

5. Further, although Applicant argues that the expected product of Subramaniam is not a liquid stream, the examiner notes that the claims do not require a liquid stream. The claims recite a non-supercritical *fluid*, which can of course be either a liquid OR a gas. As the pressure is reduced in Subramaniam et al., the liquid, supercritical CO<sub>2</sub> will change to a *gaseous*, non-supercritical fluid.

### ***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH L. MCKANE whose telephone number is (571)272-1275. The examiner can normally be reached on Mon-Fri; 5:30 a.m. - 2:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

Application/Control Number: 10/539,141

Page 5

Art Unit: 1797

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth L McKane/  
Primary Examiner, Art Unit 1797

elm  
18 January 2010